DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

m431n

October 24, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 – 06

G. Edwin Howe
President
Aurora Health Care, Inc.
3030 West Montana Avenue
Milwaukee, Wisconsin 53215

Dear Mr. Howe:

On October 4-5, 2000, representatives of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your facility, Aurora Health Care Southern Lakes, Inc. dba Memorial Hospital of Burlington, 205 McHenry Street, Burlington, WI 53105. This inspection revealed a serious regulatory problem involving the mammography at your facility, FDA certification #165670.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection the following Level 1 finding was documented at your facility:

Level 1 Non-Compliance:

1. Phantom QC records were missing (disallowed) for 11 weeks for the [redacted] mammography units located in Rooms 1 and 2. Evaluation criteria is the number of weeks missing in the worst 12-week period. The phantom image evaluation test is a mandatory weekly test.

   Note: Phantom films and/or their related Quality Control charts were disallowed because a review by the State of Wisconsin and FDA inspectors revealed that the data contained in them was falsified. Review of data from the past 12 months indicates that many phantom films allegedly produced on specific dates are multiple copies produced on limited number of days. Additional films bear more than one date; a sticker hid one of the contradictory dates on these films.

On one mammography machine [redacted] the date was hand written. On these films, patterns of artifact placement were noted for films reportedly made over multiple week periods.

The suspicious anomalies were brought to your management's attention on the first day of the inspection The person responsible for many of the records did not provide a plausible explanation for the noted patterns. Based on initials recorded on a portion of the phantom films, it appears that more than one individual produced the records in question. On the second day of the inspection your site's management advised the State inspectors that the person responsible for the past-March 2000 records had admitted that the data was falsified.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- -- the specific steps you have taken to correct all of the violations noted in this letter;
- -- each step your facility is taking to prevent the recurrence of similar violations;
- -- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- -- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Your submission should include an explanation why oversight by your site's management was unable to detect the noted record keeping problems despite their presence since at least the Fall of 1999. You should not limit your corrective actions to this single site. Rather, they should encompass oversight activities at all Aurora mammography facilities under your control.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http:www.fda.gov/cdrh/mammography/index.html.*

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

M. Edith Snyder

M. Edith Snyder
Acting Director
Minneapolis District

TWG/ccl

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